TECHNICAL REVIEW DOCUMENT
For
RENEWAL OF
OPERATING PERMIT 95OPBO150
to be issued to:

Roche Colorado Corporation
Boulder County
Source ID 0130025

Prepared by Cathy Rhodes
October 2004

I. PURPOSE:

This document will establish the basis for decisions made regarding the Applicable Requirements, Emission Factors, Monitoring Plan and Compliance Status of Emission Units covered by the renewal Operating Permit proposed for this site. The original operating permit was issued June 1, 2000 and expires on June 1, 2005. This document is designed for reference during review of the proposed permit by the EPA, the public, and other interested parties. The conclusions made in this report are based on information provided in the renewal application submitted May 26, 2004, and the significant modification application for Pharmaceutical MACT submitted on October 20, 2003. Please note that copies of the Technical Review Document for the original permit and any Technical Review Documents associated with subsequent modifications of the original Operating Permit may be found in the Division files as well as on the Division website at http://www.cdphe.state.co.us/ap/Titlev.html. This narrative is intended only as an adjunct for the reviewer and has no legal standing.

II. SOURCE DESCRIPTION:

This facility consists of a manufacturing facility for pharmaceutical intermediates, bulk pharmaceutical and some non-pharmaceutical chemicals. The facility is located in Boulder, Colorado. Boulder is classified as attainment/maintenance 1-hr ozone/VOC, carbon monoxide and particulate matter less than 10 microns (PM_{10}). Federal Class I designated areas within 100 kilometers of the plant include Rocky Mountain National Park, Eagles Nest Wilderness Area, and Rawah Wilderness Area. There are no affected states within 50 miles.

Facility wide emissions are as follows:

Pollutant	Potential (TPY)	Actual (TPY)
Particulate Matter (PM)	2	<1
PM_{10}	2	<1
Nitrogen Oxides (NO_x)	20	8
Sulfur Dioxide (SO_2)	<1	<1
Volatile Organic Compounds (VOC)	375	250

CO	11	7
HAPs	N/A	124

HAPs consist mainly of toluene, hexane, and methanol.

Potential VOC emissions are based on the summation of actual emissions for a representative two year operating period for each activity area. Potential emissions for the other pollutants are based on construction permit limits. The potential emissions are the permitted limits incorporated into the operating permit. Actual emissions are based upon APEN data.

III. Discussion of Modifications Made

Source Requested Modifications

The permittee requested the following revisions to the Operating Permit in their renewal application.

Information Page
Responsible Official is changed.
Compliance period and report dates are revised. Two months after the periods are allowed for submittal of reports.

Section II
Conditions 11.5 and 11.6 – The summary table is revised to reflect monitoring methods listed in Appendix K.

Section III
Permit shield for the asbestos requirements of 40 CFR Part 61, Subpart M are corrected to indicate only certain sections are not applicable to this facility.

MACT Requirements
On October 1, 2003 the permittee submitted a Significant Permit Modification application to incorporate specific requirements related to the Pharmaceutical MACT standard, as required in the originally issued permit. The Division held the application for inclusion in the Renewal permit, in order to include the modification along with the renewal in a single public notice and EPA review period. The permit is revised as follows to include the MACT requirements:

Section I
Condition 1.1 – Revise source description to include MACT requirements.

Condition 2.1 – Control equipment description revisions.

Condition 2.2.2 – Temperature and residence time are increased in order for Roche to use a control efficiency of 98%.

Previous Condition 2.2.6 is deleted. The permittee has installed a second/backup thermal oxidizer. The provisions for the backup ECS are moved to Section II, Condition 5.4.

Condition 2.2.7 is added to allow alternate operating scenarios while maintaining compliance with the Pharmaceutical MACT standard.

The permittee requested the addition of an Alternate Operating Scenario (AOS) for addition of new emergency generators or new temporary generators that would be subject to the initial notification of the RICE MACT (but no other requirements). These units would otherwise qualify as insignificant activities under Regulation No. 3, but the exemption from APENs and permitting do not apply to sources subject to MACT requirements. Therefore a permit modification, using the appropriate procedure, shall be applied for, for any equipment added under this scenario.

The permittee requests the addition of an AOS for switching service of storage tanks and transfer racks. The site currently has no affected sources under the Organic Liquid Distribution MACT standards because all potentially affected sources are associated with a pharmaceutical manufacturing process unit (PMPU) under the Pharmaceutical MACT or a miscellaneous chemical manufacturing process (MCPU) under the Miscellaneous Organic Chemical Manufacturing MACT. If the tank service is switched such that the equipment is no longer associated with one of the other MACT rules, the Organic Liquid Distribution MACT would apply and the requirements must be met.

The permittee requests the addition of an AOS for the Site Remediation MACT Requirements (40 CFR 63 Subpart GGGGG). The main compliance strategy for the site is included in Condition II.20. The AOS covers larger site remediation activities must be performed that do not fail within the main compliance strategy.

Conditions 5.2, 5.4 and 5.5 are revised to allow use of 98% reduction efficiency.

Section II

Condition 2.2.2 is revised to delete the requirement for a permit modification if HAP emissions exceed de minimis reporting levels. This source is an existing major source for HAPs. The existing requirement was voluntarily placed in the permit by the permittee in order to alert the public to changes in HAP emissions. Now that the MACT standard is in place, there are measures in place to ensure that any increase in HAP emissions will be controlled/minimized. The permittee is still subject to the APEN/revised APEN requirements of Regulation No. 3, as set forth in Section IV of the permit.

Condition 2.4.2 is revised to add tracking for MACT requirements for operational flexibility. The requirement to report deviations from batch procedures which increase emissions compared to standard batches is removed. The applicant requested removal of the requirement to record dates each new process is in operation. This information is required for alternative operating scenarios in Regulation No. 3.

Condition 2.4.3 is revised for inclusion of MACT operational flexibility information in the semi-annual reports. The requirements to submit copies of APENs, results of applicability determinations, emissions calculations, compliance demonstration information, and identification of applicable requirements with the semiannual report is deleted. The Division has determined that it is sufficient for the permittee to keep records for review upon request.

Condition 2.4.4 is added for reporting changes in MACT applicability.

Condition 2.5 is revised to add HAP emission calculation procedures in accordance with the MACT rule.

Condition 4 is revised to remove the voluntary leak detection and repair requirements. All piping components, etc. are now subject to the MACT, and emission estimates for VOC will be based on implementation of the MACT provisions.

Condition 5 is revised to add the backup thermal oxidizer (moved from the AOS section). Condition 5.6 is revised to allow for 98% destruction efficiency, and to replace the Regulation No. 7 monitoring requirements with the more stringent MACT monitoring requirements.

Condition 6 is revised to remove the NSPS Subpart Kb recordkeeping requirement. The EPA revised Subpart Kb on October 15, 2003 such that tanks with capacity less than 75 cubic meters are no longer subject to any requirements under Subpart Kb. Appendix K is also revised to remove this requirement. The permit shield for Subpart Kb in Section III of the permit is revised to include the entire subpart.

Condition 11.1 sets forth RACT requirements for pharmaceutical facilities. In February 1993, Roche Colorado Corporation (then Syntex) and the Division signed a Consent Order which required Roche to provide certain information and implement certain practices in order to ensure compliance with Colorado Regulation No. 7 (RACT for VOC emissions). In the order, the parties agreed that Section II.B.2 would be incorporated and made part of the operating permit for this facility.

Equipment with potential to emit less than 15 lbs of VOC per day are exempt from the RACT requirements of Regulation No. 7, Section XIV (Pharmaceutical Synthesis). In order to ensure that the potential to emit of certain equipment at the Roche Colorado facility is less than 15 lbs/day, Roche follows a program outlined in the Consent Order of calculation emissions for each process using the subject equipment. The equipment is then labeled with the process or “batch in process” name. Once the equipment has been shown by calculation to be within the 15 pound per day limit for a specific process, the Division need only examine the label on the equipment to verify that equipment is in use for an approved process and is in compliance. The permittee requests that modifications be made to the Consent Order emission calculation procedures to reflect current MACT and ACT methodologies. When the permit was originally issued, the Division determined that Consent Order language can not be modified through the

Operating Permit. The Division agrees, however, that MACT and ACT calculation procedures are more appropriate than the Consent Order methodology. Therefore, in lieu of modifying the Consent Order language, the Division has streamlined out some Consent Order language, indicating that more recent calculation procedures are more appropriate.

Conditions 12 and 13 are revised to indicate the permittee has chosen to comply with the Pharmaceutical MACT LDAR requirements in lieu of 40 CFR Part 63, Subpart I and Subpart H provisions.

Condition 14 is revised to add specific Subpart GGG MACT requirements.

Condition 19 adds Miscellaneous Organic Chemical MACT requirements. The compliance date for this MACT is May 10, 2008. The permittee has not yet determined which requirements apply, or which compliance methods will be used. This permit includes language which requires submittal of an application to incorporate specific MACT provisions when the Compliance Status Report is submitted. The Compliance Status Report is due within 150 days after the compliance date.

Condition 20 adds Site Remediation MACT requirements. The compliance date for this MACT is October 9, 2006.

Section III
The permit shield is added for the Internal Combustion Engine MACT for the existing emergency generators at the facility.
The shield for the Site Remediation MACT is applied for the groundwater remediation system.

Appendices
Appendix L is added to include the Management of Change for the Pharmaceutical MACT standard. Note that although the Management of Change addresses addition of equipment which may be subject to the MACT standards for new sources, in accordance with Section I, Condition 2.2.1, the permittee may not add new equipment to the facility unless applicable permitting requirements and other applicable requirements are met.

Other Modifications

In addition to the changes requested by the permittee, the Division has included changes to make the permit consistent with recently issued permits, to include comments made by the EPA on other Operating Permits, to reflect updated and current Regulatory language, as well as to correct errors or omissions identified during review of this renewal.

The Division has made the following revisions, based on recent internal permit processing decisions and EPA comments, to the Roche Operating Permit:

Information Page
Note regarding when semiannual and annual reports must be received is added.

Section I
Condition 1.1 is revised to reflect the new attainment status of the area.
Condition 3.1, regarding PSD status, is revised to reflect current Division permit language.
Condition 4, regarding Accidental Release provisions, is revised to reflect current Division permit language.
Condition 6 regarding Compliance Assurance Monitoring (CAM) provisions is added. As indicated in the permittee's renewal application, no units at this facility are currently subject to the CAM requirements. See revisions to Section II, Condition 11.4, below.

The following emission limits were not included in the permittee's analysis:

Condition II.5.6 – The thermal oxidizer must control emissions by at least 95%. This limitation is not subject to CAM because continuous monitoring is already required by the permit.
Condition II.11.4 – For certain VOCs, a vapor balance system or equivalent control that is at least 90% efficient must be in place for deliveries to storage tanks. Language is added to indicate that the thermal oxidizers meet the 90% equivalent control requirement.To date, no VOCs have been subject to this requirement. Language is added to indicate that if a VOC is delivered that triggers this requirement, the permittee shall determine if the CAM provisions apply. It is not expected that CAM will apply, since the thermal oxidizer would be the add on control device, and continuous monitoring is already required in the permit. Also, pre-control emissions are expected to be below the major source level.

Section II
Condition 17.2 is deleted. A separate statement regarding the status of insignificant activities is not needed in the semiannual and annual reports. The reports include insignificant activities in the list of sources/applicable requirements. (Appendix K is also revised to remove this requirement.)

Section III
Regulatory cite for Permit Shield provisions is revised to reflect recent restructuring of Colorado Regulation No. 3.

Section IV
Updated to incorporate latest version.

Appendices B and C
Updated to incorporate latest versions.

Appendix D
Update EPA Compliance Notification address.

Appendices L and M
Current Division policy does not require the attachment of complete regulations, therefore these appendices are deleted. (Appendix L is now MACT Management of Change Plan)